

REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 34, 42, 43, 45, 49 and 55 are amended, whereby claims 34-57 will continue to be pending, with claims 33, 49 and 55 being independent claims.

Support for the new claims can be found throughout the present specification (see, e.g., page 3 and the Examples).

Applicants emphasize that the amendments to claims 33, 49 and 55 are without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute the amended claims in their original, unamended form in one or more continuation and/or divisional applications.

It further is pointed out that entry of the present amendments is proper because they do not raise any new issues and do not require a further search.

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner has indicated consideration of the Supplemental Information Disclosure Statements filed May 6, June 22 and July 2, 2009 by returning signed and initialed copies of the Forms PTO-1449 submitted therein.

Claims 42, 43 and 45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 49-51, 53 and 54 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Rubino, U.S. Patent No. 3,991,176 (hereafter “RUBINO”).

Claims 34-49, 52 and 55-57 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over RUBINO in view of Gross, U.S. Patent No. 7,189,406 (hereafter “GROSS”) and Bhakoo et al., US 2003/0059396 A1 (hereafter “BHAKOO”), as evidenced by Hei et al., U.S. Patent No. 6,593,283 (hereafter “HEI”).

Claims 34-57 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Guskey et al., U.S. Patent No. 5,776,494 (hereafter “GUSKEY”).

Claims 34-36, 38-45 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-56 and 64 of copending Application No. 10/574,219.

Claims 34-36 and 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-48, 54-61 and 63 of copending Application No. 10/574,230.

Claims 34-36, 38-45 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 43, 51-53, 56-59, 64, 75 and 81 of copending Application No. 11/586,585.

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested, in view of the foregoing amendments and the following remarks.

Response to Rejection of Claims under 35 U.S.C. § 112, Second Paragraph

Claims 42, 43 and 45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The rejection essentially alleges that the language “up to … %” in the rejected claims broadens the corresponding range that is recited in the claims from which these claims depend.

Applicants respectfully traverse this rejection. The Examiner’s attention is directed to 35 U.S.C. § 112, fourth paragraph, according to which “[a] claim in dependent form shall be construed to incorporate by reference all of the limitations of the claim to which it refers.” Accordingly, the lower value of the concentration ranges recited in claims 41 and 44 is included by definition in claims 42, 43 and 45.

At any rate, the rejected claims have been amended in order to avoid any further discussions regarding this matter, thereby rendering this rejection moot.

Response to Rejection of Claims under 35 U.S.C. § 102(b)

Claims 49-51, 53 and 54 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by RUBINO. The rejection relies on Example IX in column 10, lines 1-18 of RUBINO and also argues that the term “consists of” in claim 49 is superseded by the also present term “comprises”.

Applicants respectfully (and strongly) disagree with the Examiner in this regard. At any rate, rejected independent claim 49 has been amended to make it absolutely clear that the claimed formulation is free from zirconium containing antiperspirant active ingredients and contains the recited components (a), (b) and (c) in ratios which result in gelling.

It is pointed out in this regard that the buffer described in the first part of Example IX, while being free of zirconium, is disclosed to be a solution and thus does apparently not comprise Chlorhydrol, citric acid and water in ratios which result in gelling.

Response to Rejection of Claims under 35 U.S.C. § 103(a) over RUBINO as Primary Document

Claims 34-49, 52 and 55-57 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over RUBINO in view of GROSS and BHAKOO, as evidenced by HEI.

The rejection concedes that RUBINO does not use mandelic acid as the α -hydroxycarboxylic acid in the aluminium-zirconium antiperspirant complexes disclosed therein but essentially alleges that GROSS renders the use of mandelic acid in the complexes of RUBINO obvious to one of ordinary skill in the art. Alternatively, the rejection alleges that it would have been obvious to include mandelic acid in the compositions of RUBINO because BHAKOO teaches that malodor is the result of microorganisms and that generally deodorants work through an antimicrobial ability to decrease the population of microorganisms and because HEI teaches that mandelic acid possesses antimicrobial properties.

Applicants respectfully traverse this rejection as well. Regarding the rejection over RUBINO in view of GROSS the remarks set forth in the response to the previous Office Action are incorporated herein.

With respect to amended independent claim 49 submitted herewith it is pointed out again that the antiperspirant active ingredient of the formulation recited therein is free from zirconium containing antiperspirant active ingredients and contains the recited components (a), (b) and (c) in ratios which result in gelling. In contrast, the antiperspirant active ingredient of RUBINO comprises

a combination (complex) of a basic aluminum compound, a zirconium compound and a hydroxycarboxylic acid (see, e.g., abstract of RUBINO). Neither RUBINO nor GROSS teaches or suggests that in the complex of RUBINO the zirconium compound can be dispensed with. RUBINO and GROSS also fail to teach or suggest that in the compositions of RUBINO the aluminum compound, the hydroxycarboxylic acid and water should be present in ratios which result in gelling. For these reasons alone, RUBINO in view of GROSS are unable to render obvious the subject matter of claim 49 (and the claims dependent therefrom, such as claim 52). It further is not seen that BHAKOO or HEI are able to cure these deficiencies of RUBINO and GROSS.

Amended independent claims 34 and 55 submitted herewith both recite, *inter alia*, the presence of components (a), (b) and (c) in ratios which result in gelling and the presence of mandelic acid in component (b) of the cosmetic or dermatological formulations claimed therein.

It is not seen that any of RUBINO, GROSS, BHAKOO or HEI teaches or suggests that in the compositions of RUBINO the antiperspirant active ingredient, mandelic acid and water are to be present in ratios which result in gelling. On the contrary, the water containing antiperspirant of Example IX of RUBINO primarily relied on by the Examiner is disclosed to be a solution (and does not even contain mandelic acid). Moreover, according to, e.g., the abstract of RUBINO the antiperspirant aluminum zirconium complexes disclosed therein may be used in conventional anti-perspirant forms, including aqueous solutions, aerosol sprays, creams, lotions and cream sticks. Nothing in these disclosures teaches or suggests that it would be desirable for these complexes to be present in combination with water and mandelic acid, let alone in ratios which result in gelling. It is not seen that any of GROSS, BHAKOO or HEI are able to cure these deficiencies of RUBINO. For

the above reasons alone, RUBINO, GROSS, BHAKOO and HEI fail to render obvious the subject matter of claims 34 and 55 (and the claims dependent therefrom).

Further, it has already been pointed out in the response to the previous Office Action that while RUBINO discloses a number of hydroxycarboxylic acids for use in the antiperspirant complexes taught therein, the list of exemplary acids (a total of 12 acids) does not include mandelic acid, and neither does this list include any aromatic acid (see col. 4, lines 23-26 of RUBINO). In other words, all of the specific acids mentioned by RUBINO are non-aromatic acids, thereby failing to provide an apparent reason for one of ordinary skill in the art to use mandelic acid instead of any of the 12 specific acids specifically mentioned in RUBINO.

GROSS is unable to cure this deficiency of RUBINO. In particular, there is no motivation for one of ordinary skill in the art to combine the teachings of RUBINO and GROSS. Specifically, RUBINO relates to anti-perspirant formulations for application to the human axilla whereas GROSS relates to dermatological compositions for use by consumers for the topical treatment of skin aging, acne, etc. and for the improvement of skin appearance. It is not seen that someone who wishes to improve or modify the antiperspirant formulations of RUBINO for application to the human axilla is interested in a document which relates to a formulation which is supposed to treat aging of the skin or acne and improves the appearance of the skin.

The Examiner's comments in this respect are noted. The Examiner "believes that applicant has underestimated the human vanity and the extremes to which people go in the pursuit of beauty" and states that GROSS was cited "mainly to show that mandelic acid is an α -hydroxycarboxylic acid which is suitable for topical application to human skin and only secondarily that it provides

improvements in skin-appearance”.

In this regard, Applicants submit that the question here is not whether certain individuals would be vain enough to worry about the appearance of their armpits, but whether one of ordinary skill in the art of cosmetic compositions would have an apparent reason to include mandelic acid in the antiperspirant compositions of RUBINO merely because mandelic acid is mentioned in GROSS in connection with a method for improving the appearance of the skin.

At any rate, according to GROSS mandelic acid is not intended to be kept on the skin for extended periods of time but is to be used only in the first step of a two-step acid peel for the skin wherein in a first step a first composition comprising a skin renewing acid component (for example, mandelic acid) is employed followed, in a second step, by the application of a second neutralizing composition which comprises an alkaline agent (which is used to neutralize the renewing acid component).

Further, according to col. 3, lines 56 - 67 of GROSS preferably the composition for the first step of the two-step acid peel “includes at least one alpha hydroxy acid selected from the group consisting of glycolic acid, lactic acid, malic acid, tartaric acid, citric acid and ascorbic acid.” Mandelic acid and other acids (azelaic acid, glyceric acid, tartronic acid, gluconic acid, benzylic acid, pyruvic acid, ethyl pyruvate, 2-hydroxybutyric acid, and salicylic acid) are mentioned only as examples of “other preferred skin-renewal stimulating acids”. In line therewith, none of the compositions of Examples 1 to 3 of GROSS comprises mandelic acid.

In other words, mandelic acid clearly is not the only α -hydroxycarboxylic acid which is mentioned in GROSS and does not even belong to the group of the particularly preferred acids (for the first step of the two-step peel disclosed therein). In this regard, it also is pointed out that even in

the case of GROSS the particularly preferred acids are non-aromatic, which is consistent with the teaching of RUBINO (which mentions exclusively non-aromatic acids, see above).

Regarding the rejection over RUBINO in view of BHAKOO and HEI, Applicants submit that the Examiner's allegations appear to be somewhat far-fetched. Even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to include a deodorant in the compositions of RUBINO and would for this purpose choose an antimicrobial agent in view of the teaching of BHAKOO, it is not seen that there would be an apparent reason for one of ordinary skill in the art to choose mandelic acid as the antimicrobial agent.

In particular, BHAKOO explicitly teaches in paragraphs [0006] and [0007] thereof that the antimicrobial benefit and subsequent malodor reduction obtained with typical antimicrobial agents which are used as deodorants, particularly many hours after application, "is not always excellent", and that the inventors of BHAKOO have discovered synergistic mixtures of picolinic acid and a peroxy species or equivalent source thereof that can achieve the target of providing an excellent antimicrobial benefit and subsequent malodor reduction. BHAKOO does not appear to mention mandelic acid, i.e., not even as an antimicrobial agent which is comparable with the typical antimicrobial agents which are used as deodorants.

HEI merely teaches antimicrobial compositions which contain antimicrobially active solvents as set forth in col. 7, lines 1-45 thereof and preferably contain an (optional) additional antimicrobial agent which can be dissolved or dispersed in the antimicrobially-active solvent or in the diluting solvent (col. 10, lines 22-25). Mandelic acid is included in a laundry list of specific compounds and types of compounds of most diverse structures which may be used as additional

antimicrobial agent. According to the paragraph bridging columns 10 and 11 of HEI, compositions which contain “such optional additional antimicrobial agents appear to have substantially greater antimicrobial effectiveness than comparison aqueous solutions or dispersions containing the additional antimicrobial agent alone.”

In other words, HEI makes it clear that if used alone, compounds such as, e.g., mandelic acid are not particularly effective as antimicrobial agents and clearly does not teach or suggest that mandelic acid by itself would be useful as deodorant.

It further is pointed out that although HEI discloses a large number and variety of potential uses for the antimicrobial compositions disclosed therein (see col. 11, line 58 to col. 13, line 32) the application of these compositions to human skin is not taught or suggested. The closest disclosure in this regard appears to be in col. 12, lines 28-30 of HEI where it is stated that “[t]he antimicrobial compositions of the invention can be used for treating skin diseases on animals (especially mammals)”.

Applicants submit that for at least of all of the foregoing reasons, the rejection of claims 34-49, 52 and 55-57 under 35 U.S.C. § 103(a) over RUBINO in view of GROSS and BHAKOO, as evidenced by HEI is without merit and should be withdrawn, which action is respectfully requested.

Response to Rejection of Claims under 35 U.S.C. § 103(a) over GUSKEY

Claims 34-57 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over GUSKEY. The rejection essentially alleges that GUSKEY teaches a topical pharmaceutical composition comprising at least one active agent, a gelling agent, and an anhydrous solvent and that

among the active agents, aluminum and aluminum-zirconium chlorohydrate and mandelic acid are mentioned. The rejection also notes that although GUSKEY teaches that an anhydrous solvent is used, GUSKEY also teaches that the anhydrous solvent may contain up to 5 % of water.

Applicants respectfully traverse this rejection as well. In particular, it is pointed out that all of the present independent claims submitted herewith recite, *inter alia*, that antiperspirant active agent, α -hydroxycarboxylic acid and water are present in ratios which result in gelling. By teaching that the anhydrous solvent most preferably contains zero percent of free or added water (col. 10, lines 29-35), GUSKEY makes it clear that water is not only a non-essential but even an undesirable component of the compositions disclosed therein, thereby clearly failing to provide an apparent reason for one of ordinary skill in the art to pay attention to the water content of the compositions (other than to keep the water content at a minimum), let alone to employ water in an amount which results in a ratio with respect to antiperspirant active agent and α -hydroxycarboxylic acid which results in gelling.

In this regard, it also is pointed out that even if one were to assume, *arguendo*, that the concentration of water in the compositions of GUSKEY can be unlimited, there would be no apparent reason for one of ordinary skill in the art to adjust the amount of water with respect to antiperspirant active agent and α -hydroxycarboxylic acid so that the ratio of these three components results in gelling because the compositions of GUSKEY already contain a gelling agent (as acknowledged by the Examiner). This is yet another reason why GUSKEY is unable to render obvious the subject matter of any of the claims submitted herewith.

Further, while GUSKEY mentions both aluminum or aluminum-zirconium chlorohydrate and mandelic acid as examples of the many types of active agents which can be present in the compositions disclosed therein (i.e., antiseptic or antibacterial actives, antifungal agents, hormones, exfoliating agents, topical analgesics, sunscreen actives, antioxidants and vitamins, to name but a few), it is pointed out that mandelic acid is mentioned as an example of an exfoliating agent and aluminum and aluminum-zirconium chlorohydrates are mentioned as examples of antiperspirant actives which can be present in the compositions of GUSKEY. It is not seen that one of ordinary skill in the art has an apparent reason to include an antiperspirant active in a composition for exfoliating the skin or to include an exfoliating agent in an antiperspirant. This is yet another reason why GUSKEY fails to render obvious the subject matter of any of the present claims.

Applicants submit that for at least all of the foregoing reasons, the rejection of claims 34-57 under 35 U.S.C. § 103(a) over GUSKEY is unwarranted, wherefore withdrawal thereof is respectfully requested.

Response to Provisional Rejections of Claims

Claims 34-36, 38-45 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-56 and 64 of copending Application No. 10/574,219; claims 34-36 and 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 46-48, 54-61 and 63 of copending Application No. 10/574,230; and claims 34-36, 38-45 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as

allegedly being unpatentable over claims 43, 51-53, 56-59, 64, 75 and 81 of copending Application No. 11/586,585.

Applicants respectfully request that the above provisional rejections be held in abeyance until the Examiner has indicated allowable subject matter. Applicants will then decide whether the filing of one or more terminal disclaimers is appropriate.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance (with the possible exception of obviousness-type double patenting issues). If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
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